EXHIBIT 18

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Plaintiffs, v. MODERNA, INC. and MODERNATX, INC., Defendants.	)	C.A. No. 22-252-MSG
MODERNA, INC. and MODERNATX, INC., Counterclaim-Plaintiffs, v. ARBUTUS BIOPHARMA CORPORATION and GENEVANT SCIENCES GmbH, Counterclaim-Defendants.	)	

DECLARATION OF DANIEL ØSTERBY
IN SUPPORT OF MODERNA'S OPPOSITION TO
PLAINTIFFS' MOTION TO COMPEL

I, Daniel Østerby, hereby declare as follows:

1. I am currently employed by Moderna as a Senior Director in the Global Quality Systems and Compliance department. I have held the position since May 2023. I have personal knowledge of the facts stated in this declaration or have become aware of such facts through my role at Moderna.

2. Moderna's COVID-19 Vaccine is an FDA-approved drug product. Moderna's COVID-19 Vaccine is also a GMP product, meaning it complies with Good Manufacturing Practice requirements. Good Manufacturing Practice is a system of both procedures and documentation that ensures products are consistently produced and handled in accordance with specified quality standards. Due to these documentation requirements, Moderna must maintain written procedures

detailing how its COVID-19 vaccine is manufactured and handled, for example. If the handling or storage of a drug product needs to deviate from the prescribed procedures, a new protocol or plan needs to be prepared, approved, and implemented to define how that material will be treated.

3. Federal Regulations require Moderna to keep "reserve samples," also referred to as "regulatory retains," of drug product that are "representative of each lot or batch," specifying that the company must keep "at least twice the quantity necessary to perform all the required tests." 21 C.F.R. 211.170(b). To comply with these requirements, Moderna has in place Standard Operating Procedures that define how these samples are managed.

4. Federal Regulations require that the "reserve samples" be retained "for 1 year after the expiration date of the drug product." 21 C.F.R. 211.170(b)(1). These samples are required in case, for example, an adverse event is reported for one of Moderna's COVID-19 vaccines that necessitates testing of that batch. It is therefore imperative that these retains are preserved according to Moderna's procedures.

5. Following one year after expiry, Moderna is generally not required to maintain these samples, but may need to rely on such samples for other business reasons. Certain batches, such as those used in clinical trials, for example, may also be subject to additional regulations, necessitating longer storage of regulatory retains.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct to the best of my knowledge.

Executed on this January 5, 2024

DocuSigned by:
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Daniel Østerby